

Human Health Risk Assessment Methods and Policies

Issue

What changes (if any) should Ecology make to the Model Toxics Control Act (MTCA) cleanup regulation given current scientific information and regulatory guidance on human health risk assessment methods?

Problem Statement

The risk assessment methods in the MTCA cleanup regulation are based on scientific information and regulatory guidance available at the end of the 1990s.¹ Since the 2001 amendments, there have been several important scientific and regulatory developments relevant to establishing risk-based cleanup levels. This information raises several questions about the current MTCA cleanup regulation:

- Whether MTCA terms and definitions need to be updated based on recent EPA guidance?
- Whether (and if so, how) multiple exposure pathways (e.g., ingestion, dermal contact, and inhalation) should be considered when establishing soil cleanup levels?
- Whether the exposure parameters used when calculating risk-based cleanup levels should be revised to incorporate early-life stage exposure pathways and parameters corresponding to critical windows of susceptibility for the developing fetus, infants, and young children where cancer may be expressed later in life?
- Whether the toxicological parameters used when calculating risk-based cleanup levels should account for the potential that early life exposure to chemical carcinogens may increase the risk of developing cancer later in life?
- Whether the methods and policies used to establish risk-based cleanup levels for indoor and outdoor air need to be revised based on recent EPA guidance?

Background

The MTCA cleanup regulation provides methods and policies and procedures establishing cleanup levels based on human health protection. The original cleanup standards were adopted

¹ In this issue summary the terms MTCA cleanup regulation and MTCA rule are used interchangeably and refer to Chapter 173-340 WAC.

in 1991. The risk assessment methodologies included in the original rule were based on the scientific and regulatory guidance available at that time. Key features include:

- Cleanup levels are based on protecting the most sensitive populations, including pregnant women, developing fetuses, and children.
- Cleanup levels for ground water, surface water, soil, and air are based on the “reasonable maximum exposure” that a person might encounter. The reasonable maximum exposure is designed to represent a high end (but not worst case) estimate of individual exposures.
- Cleanup levels corresponding to the reasonable maximum exposure are based on exposure parameters (e.g., soil ingestion rate, body weight) included in EPA guidance.
- Cleanup levels are based on toxicological parameters (cancer slope factors and reference doses) developed by EPA scientists.

Ecology reviewed the available scientific literature and regulatory guidance when preparing the 2001 rule amendments. Based on that review, Ecology updated the risk assessment methods used to establish cleanup levels. During that rulemaking, Ecology modified the methods for establishing soil cleanup levels to include consideration of both soil ingestion and dermal contact. For petroleum mixtures, the standard equation includes both pathways. For other chemicals, dermal contact is evaluated only when changes to the standard equation results in site-specific cleanup levels that are significantly higher than those calculated using standard equations.

New Scientific and Regulatory Information Since 2001 Rule Revisions

Since the 2001 rule revisions, there have been several important scientific and regulatory developments relevant to this rulemaking issue.

- EPA Risk Assessment Guidance: EPA has published several new guidance materials relevant to the human health risk assessment methods used to establish cleanup levels. This includes cancer risk assessment guidelines, methods for evaluating dermal exposure, child exposure assessment, and methods for evaluating inhalation risks.^{2 3 4 5}
- National Research Council (NRC) Reports: Several NRC expert panels have prepared reports and recommendations on risk assessment methods and policies.^{6 7} NRC scientific

² U.S. Environmental Protection Agency. 2005. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum. EPA/630/P-03/001F.

³ Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Final July 2004. EPA/540/R/99/005.

⁴ U.S. Environmental Protection Agency. 2006. Child-Specific Exposure Factors Handbook (External Review Draft). National Center for Environmental Assessment. Office of Research and Development. EPA/600/R/06/096A.

⁵ Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment) Final January 2009. EPA/540/R/070/002.

⁶ National Research Council. 2008. Science and Decisions: Advancing Risk Assessment. Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. National Academy Press. Washington DC.

panels have also completed reports and recommendations on risk assessment issues surrounding particular chemicals.⁸

- World Health Organization Report: An international scientific panel completed an evaluation of the disproportionate health risks to children from exposure to chemicals.⁹
- Risk Equations: EPA Regions 3, 6, and 9 and the Oak Ridge National Laboratory (ORNL) have jointly developed risk-based equations that evaluate the toxicity and assess the risks from concurrent ingestion, dermal, and inhalation routes of exposure to chemical contaminants.¹⁰

Rulemaking Options Being Evaluated

Ecology is considering several options for addressing these issues during the current rulemaking process. These include:

Update Terms and Definitions: Under this option, Ecology would revise the rule to maintain consistency with EPA 2005 cancer risk guidelines and 2009 inhalation risk assessment guidance.

Concurrent Exposure: Under this option, Ecology would modify the rule to more explicitly define when and how dermal contact must be considered when establishing soil and ground water cleanup levels for some or all chemicals. Ecology is evaluating dermal and inhalation routes of exposure in risk based cleanup decisions. This includes evaluating whether and how to account for dermal and inhalation exposures that occur concurrently with incidental soil ingestion when establishing soil cleanup levels.

Modifying the MTCA Cleanup Equations Based on New EPA Inhalation Risk Guidance: Under this option, Ecology would modify the equations in WAC 173-340-750 to reflect recent EPA inhalation risk guidance. Specifically, EPA stopped using oral – to – inhalation extrapolation because the inhalation toxicity values from the National Center for Environmental Assessment (NCEA) are now available on the Integration Risk Information System (IRIS). Ecology is considering discontinuing the assumption that the adverse effects from oral and inhalation exposures and the corresponding toxicity values are equivalent. This would lead Ecology to modify the MTCA cleanup equations to use the inhalation toxicity values directly. This would also include modifying the MTCA equations to reflect the toxicity metrics in the EPA

⁷ NRC review of OMB risk assessment review

⁸ National Research Council. 2006. Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment. Committee on EPA's Exposure and Human Health Reassessment of TCDD and Related Compounds. National Academy of Sciences. National Academy Press. Washington DC.

⁹ World Health Organization, 2006. Principles For Evaluating Health Risks In Children Associated with Exposure To Chemicals, Environmental Health Criteria 237.

¹⁰ EPA Region 3/6/9 Risk Based Equations: http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

guidance.¹¹ Ecology is considering modifying the MTCA cleanup equations to use the inhalation toxicity values directly in the equations.

Early-Life Stage Exposure and Risks: Under this option, Ecology would modify the rule to incorporate recent EPA guidance on early-life stage exposure. Ecology is currently evaluating the need for age adjustments to account for differences in exposure patterns between children and adults for carcinogens. Ecology is also considering age dependent adjustment factors for carcinogens that have an early life exposure that may express a carcinogenic response later in life. Consideration of age adjustment factors will change the exposure duration currently used by MTCA to establish soil risk based cleanup levels.

Factors to Consider when Selecting Options

Developing amendments to the MTCA cleanup regulation will require considering and balancing a number of issues and interests. Ecology believes that the following factors need to be considered when evaluating options for addressing this issue:

- How frequently have people used Modified Method B to establish soil cleanup levels that take into account the dermal contact pathway?
- How frequently have people used Modified Method C to establish soil cleanup levels that take into account the dermal contact pathway?
- Will addressing these issues be consistent with federal and state regulations and technical information and guidance?
- Will addressing these issues help establish consistent standards and methodologies for establishing cleanup levels protective of human health?

Proposed amendments must also satisfy several regulatory goals, including the following:

- Providing for the selection of cleanup actions that protect human health and the environment.
- Developing scientifically and legally defensible cleanup standards.
- Providing consistent standards and methodologies for assessing and managing risk.
- Providing flexibility to address site-specific factors.

¹¹ Currently, the EPA toxicity metrics (Reference Concentrations (RfCs) and Inhalation Unit Risks (IURs, InhURs)) must be converted to Reference Doses (RfDs) and Cancer Slope (Potency) Factors which are the toxicity metrics used in the MTCA rule. The Supplemental Guidance for Inhalation Risk Assessment recently published by EPA uses RfCs in units of mg/m³ and IURs in units of (µg/m³)⁻¹ directly in the equations for establishing cleanup levels from the inhalation exposure pathway.